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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,459	08/26/2003	Thomas Yung-Hui Chien	29985/01-530	5094

4743 7590 05/03/2006

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EXAMINER

WEBB, SARAH K

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/648,459

Applicant(s)

CHIEN ET AL.

Examiner

Sarah K. Webb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected:
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/03, 11/04, 3/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 17 and 30 are objected to because of the following informalities: "the cooling" is not mentioned in independent claims 14 and 27 from which these claims depend, but in the preceding claims 16 and 29. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1,2,4,8,9,11-15,18,19,21,23,27, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,292,321 to Lee.

Lee discloses a stent delivery catheter with an inner tube (14), outer tube (24), heating element (35), and a balloon (20) extending between the distal tip of the outer tube and the distal end of the inner tube. A stent (19) is mounted on the balloon (column 7, line 59 through column 8). As shown in Figure 1, the maximum outer diameter of the tapered distal tip is equal to the compressed diameter of the stent (19). The heating element (35) is a braided wire and is connected to electrical wires (31 and 34) (column 8, lines 39-58). The device includes a temperature-monitoring element (36) (column 8, lines 59-66). Lee discloses a method of using the device to deliver the stent that meets the claim limitations, including the step of monitoring temperature (column 11, lines 1-10).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 3 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee in view of US Patent No. 5,035,694 to Kasprzyk et al.

Lee fails to form the heating element as a coil, but forms the heating element has a braided wire sleeve (35) (column 8, lines 53-58). Kasprzyk discloses another balloon catheter with a heating element disposed on an inner tube within the balloon cavity. Kasprzyk teaches that the heating element can be a coiled wire (51), as shown in Figure 4. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the braided heating element of Lee as a coiled wire, as taught by Kasprzyk, as this is simply a substitution of functionally equivalent structures.

4. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee in view of US Patent No. 6,270,521 to Fischell et al.

Lee fails to include radiopaque markers at the proximal and distal ends of the balloon, but does use a radiopaque dye in the inflation fluid so that the balloon can be monitored (column 10, lines 45-48). Fischell discloses a balloon catheter with very similar features to Lee, including an inner tube (12), outer tube (11), balloon (18), and tapered tip (15). Fischell teaches that a stent delivery balloon catheter should have radiopaque markers (13P and 13D) at the proximal and distal ends of the balloon so

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that the stent can be centered with respect to the stenosis (column 6, lines 3-4). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include radiopaque markers at the proximal and distal ends of the balloon of the Lee device, as Fischell teaches that this helps center the stent.

5. Claims 5-7,16,17,24-26,29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee in view of Lashinski.

Lee fails to form the stent from a shape-memory metal, such as Nitinol. Lashinski discloses another heated balloon catheter. Lashinski teaches that this type of device is advantageous for delivering shape-memory stents because a sheath is not required and control is maintained over the position of the stent during expansion (column 2, line 34 through column 3, line 17). Lashinski teaches that a shape memory Nitinol stent can be crimped onto the balloon (column 4, line 2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to deliver a shape-memory stent with the Lee device, as Lashinski teaches that the expansion and position of this type of stent may be highly controlled with a heated balloon catheter. The Nitinol stents may also have more desirable mechanical properties for a particular procedure than the polymeric stents disclosed by Lee.

Regarding the cooling step, Lee discloses the use of a cooling fluid injected into the balloon cavity to cool the stent (column 11, lines 20-65) and Lashinski discloses the use of a fluid to contract the stent onto the balloon (column 6, lines 26-35). Considering these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to inject a cooling liquid into the balloon during

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insertion of the stent if it is necessary to prevent premature expansion of the stent due to body heat.

6. Claims 22 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee in view of US Patent No. 6,174,327 to Mertens et al.

Lee simply does not state how the device is packaged, but Mertens teaches that a removable sheath can be disposed over the stent and removed before insertion (column 9, lines 12-20). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a removable sheath over the stent of Lee, as taught by Mertens, in order to protect the stent during shipping and storage.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K. Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW
4/26/06

SW
Julian W. Woo

JULIAN W. WOO
PRIMARY EXAMINER